

146223.00001
Response to OA
DUE: 4-3-02



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,258	04/03/2001	Sita R. Kaura	146323.00001	2051

7590 01/03/2002

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

6

DATE MAILED: 01/03/2002

REC'D 1-15-02 P3F8M

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,258	KAURA, SITA R.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 and 23-48 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 30 and 32-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 23-29 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 14-18 and 23-48 are pending.

Applicant's election with traverse of loratadine and montelukast sodium in Paper No. 4 received December 10 2001 is acknowledged. The traversal is on the ground(s) that the Examiner did not state that "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended."; the traverse is also on the ground that the Examiner did not state that "upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141". The examiner would like to express the appreciation that the applicant points out the two statements cited by the MPEP. This is not found persuasive because, as pointed out by the applicant, by definition the examiner must extend the search to other species should the elected species be found free of prior art. Therefore, even though the Examiner did not expressly state the two statements above in the previous office action, the election of species requirement is still proper because the search for all species encompassed by the claims presents an undue burden to the Office, as discussed in the previous office action mailed September 13, 2001.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of the invention of Group I, claims 1-15, in Paper No. 4 is acknowledged. The newly added claims 23-35 in amendment submitted

December 10, 2001 are also drawn to composition. Therefore, claims 23-35 are considered to be in the invention of Group I.

Claims 16-18 and 36-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4, received December 10, 2001.

Claims 30, and 32-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4 received December 10, 2001.

The claims have been examined herein to the extent they read on the elected invention and species.

Claim Objections

Claims 23, 24, 29, and 31 are objected to because of the following informalities: the term "bronchudilator" is apparently misspelled as "broncodilator". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15, 23-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlen et al. (WO 97/28797) in view of Katzung ("Basic & Clinical Pharmacology", 6th ed., 1995, page 312-314).

Dahlen et al. teaches an asthma treating composition comprises Loratadine and Montelukast sodium (See particularly page 5, Example, whole page).

Dahlen does not expressly teach the asthma treating composition contains a adrenergic bronchodilator such as albuterol.

Katzung teaches that albuterol is useful in treating asthma (See particularly page 314, col. 1, first paragraph).

It would have been obvious to one skill in the art when the invention was made to incorporate albuterol into the asthma treating composition of Dahlen et al.

One of ordinary skill in the art would have motivated to incorporate albuterol into the asthma treating composition of Dahlen et al. because combining agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
December 30, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600